IN THE SPECIFICATION:

1. Effective Filing Date.

Background

In Paragraph 1 of the Office Action, the United States Patent and Trademark Office acknowledged the filing of a Continued Prosecution Application (CPA) on November 28, 2001, based on an earlier filed patent application with a filing date of March 29, 1999. The CPA was filed as part of a Petition for Revival of an Application for a Patent Abandoned Unintentionally under 37 CFR 1.137(b). The reason that the application was abandoned was the malpractice of the original applicant's attorney, a discussion of which is contained within an affidavit by the inventor, which was contained in the Petition. As part of the malpractice, the original patent application had been filed with a specification that was skeletal, at best. The original application contained Claims 1 - 28. To put the application in condition for review by the United States Patent and Trademark Office, the applicant filed the CPA canceling the claims of the original application and replacing them with new claims 29 through 39.

The United States Patent and Trademark Office asserts that because all of the original claims were canceled, the instant application is not entitled to the filing date of its parent application, citing MPEP 706.07(h) row 14. The applicant respectfully asserts that this is an improper reading of the MPEP

and is inconsistent with the U.S. Patent statutes and regulations.

Analysis

35 USC § 111 establishes the requirements for the contents of a patent application. Under that section, a nonprovisional application must contain a specification as prescribed by 35 USC § 112. Section 112 states that a specification shall contain a written description of the invention and "shall conclude with one or more claims, particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 USC § 112, second paragraph.

Apparently, the United States Patent and Trademark Office is asserting that because the claims of the original application, as filed in 1999, were canceled, there has been a violation of 35 USC § 112, second paragraph. In fact, the applicant respectfully asserts that there has been no violation of this statute. The purpose of 35 USC § 112, second paragraph, is to require an applicant to assert in a claim(s) what he believes to be his invention. Obviously, it is impossible for the USPTO to review an application for patentability if it does not contain a claim for the subject matter which the applicant believes to be the invention. Just as obviously in this case, the subject matter which the applicant believes to be his invention is set out in new claims 29 through 39.

The applicant asserts that the statement within Row 14 of MPEP 70607(h) only applies where there are no claims present in a CPA application, not a situation where new claims have been asserted in a preliminary amendment, which accompanies and is a part of the CPA application. Support for this interpretation of the MPEP is set forth in MPEP § 601.01(e). This provision discusses the requirement of at least one claim being present in a nonprovisional application and states as follows:

> If a nonprovisional application does not contain at least one claim, or is accompanied by a preliminary amendment which cancels all claims, and fails to simultaneously submit any new claim(s), . . . a "Notice of Incomplete Application" will be mailed to the applicant(s) indicating that no filing date has been granted...(emphasis supplied)

This provision of the MPEP specifically recognizes that 35 USC § 111 and 112 require that a claim be present in the application, as filed, but not necessarily that the claim be present in the application itself. Pursuant to MPEP 601.01(e), the claims of the application may be presented in a preliminary amendment filed simultaneously with the application. Clearly there is no logic to requiring an applicant to retain a claim from an original application which the applicant and the USPTO have recognized has questionable validity. (Note that the claims as originally filed had previously been rejected by the USPTO in a first Office Action.) In fact, the applicant may be forbidden to continue to prosecute a claim where the applicant is aware of its

questionable patentability.

In this situation, as suggested by MPEP § 601.01(e), a preliminary amendment was filed which canceled all claims from the original application while simultaneously submitting new claims. By this procedure the applicant has satisfied the requirements of 35 USC Sections 111 and 112.

Accordingly, the applicant asserts that the effective filing date of this application is its original filing date of March 29, 1999. The applicant requests that this objection to the effective filing date be withdrawn.

2. Substitute Specification.

Background

In paragraph 3 of the Office Action, the USPTO asserts that "new matter" has been entered into the application. The USPTO specifically asserts that there is "numerous newly-added material." To this assertion the applicant agrees.

The USPTO, however, goes further and asserts that none of this newly-added material is supported by the disclosure from the original application. Further, the USPTO asserts that the entire specification fails to meet the requirements of 35 USC § 132. The USPTO also requests that the new matter be canceled in the reply to the Office Action.

In Paragraph 4 of the Office Action, the USPTO further asserts

that the Substitute Specification has not been entered as it does not conform to 37 CFR 1.125(b) and (c) because it improperly incorporates essential subject matter to the disclosure without sufficient basis in the original application.

Finally, the USPTO states that the applicant does not provide any affidavit or declaration stating that the amendatory material consists of the same material incorporated by reference in the referencing application. Thus, the USPTO concludes that the Substitute Specification can not be entered as it does not conform to 37 CFR 1.125(b). The applicant respectfully traverses this determination.

Analysis

The original application that was filed on March 29, 1999, contained a limited disclosure of the invention. In the Field of the Invention, however, that application did state as follows:

> More particularly, the present invention relates to the use of a histamine H_2-receptor antagonist with antipsychotic and mood stabilizing drugs to control weight.

This general description of the invention is restated in the Summary Of The Invention, first paragraph, and in the first paragraph of the Description Of The Preferred Embodiment of the original application as filed. In particular, the Summary Of The Invention, stated as follows:

> The present invention prevents and

> reverses weight gain associated with the use of olanzapine and other antipsychotic drugs. The combination of psychoactive drugs and histamine H_2-receptor antagonists may represent a combined single dose delivery system or multiple drug regimen taken at pre-selected times. The psychoactive drugs are dosed as recommended by the manufacturer and the histamine H_2-receptor antagonists are dosed as for use in maintenance treatment of duodenal ulcer. (emphasis supplied.)

This outline of the use of a combination of drugs for weight loss is also set forth in Figure 1 of the original application, which shows the combination of either an antipsychotic drug (12) or a mood stabilizing drug (14) with a histamine H_2-receptor antagonist (16) to control weight. Particular examples of each of these types of drugs are contained in the boxes in Figure 1. The particular choices of drugs are also disclosed in a list of reference numerals contained in the drawings of the original application, as well as in the Description of the Preferred Embodiment. In addition to disclosing particular drugs for a particular process or method, the preferred quantities of each of the drugs is also disclosed.

Because the application, as originally filed, was deficient, as acknowledged by the USPTO in its Office Action of November 24, 1999, the applicant filed a "substitute specification" under 37 CFR 1.125(b), when he filed his Petition for reviewal of the application. The substitute specification was contained in a preliminary amendment, which was filed as part of the Petition. The

applicant and his counsel specifically declare that no new subject matter was introduced in this Substitute Specification. A detailed analysis of the Substitute Specification and the basis for each disclosure therein either in the original application, as filed, or in prior art, particularly the Physician's Desks Reference ("PDR"), which was well known at the time to a person skilled in the art, follows. (Note that the PDR was specifically discussed in the preliminary amendment and was included as one of the references cited in the Information Disclosure Statement, which was also filed with the Petition.)

Analysis of Substitute Specification.

Page 1 of the Substitute Specification contains the Title, Technical Field and begins a discussion of the Background of the Invention. The subject matter of the title and the technical field are clearly supported in the original application, as filed. (See the Summary of the Invention, Description of a Preferred Embodiment and Claims of the application as filed.)

With regard to the remaining information contained within the Background in the Invention, all the subject matter was contained in the original application and was well known at the time of the filing of the original application, including particularly the use of olanzapine as an antipsychotic and mood-stabilizing drug. (See particularly the Summary of the Invention of the original application.) In particular, the second paragraph of the

substitute specification discusses the problem of weight gain when using a typical anti-psychotic. This discussion is merely a restatement of what is stated in the Description of the Prior Art, the first paragraph of the Summary of the Invention, the first paragraph of the Description of the Preferred Embodiment and Claim 1 of the original application, as filed.

The second paragraph on page 2 of the Substitute Specification discusses the mechanism of weight gain caused by the use of anti-psychotics, such as olanzapine, and cites two articles, both of which were well known at the time of the filing of the original application, as one is dated in 1997 and the other is dated in 1998. In addition, see the Description of the Prior Art and first paragraph of the Summary of Invention, of the original application, as filed.

The third page of the Substitute Specification includes a Summary of the Invention. The Summary of the Invention merely describes the combination of a psychoactive drug and histamine H_2-receptor antagonist for the treatment of weight gain. This is a summary of the invention that was disclosed in the original application, as filed, and is disclosed in that original application, in the Field of the Invention, Description of Prior Art, Summary of the Invention, paragraph 1 of the Description of the Preferred Embodiment, Claim 1, and the Abstract Of The Disclosure.

The second paragraph of the Summary of the Invention of the Substitute Specification lists specific antipsychotic drugs, mood stabilizing drugs, and histamine H_2-receptor antagonists that can be used in the invention, all of which are disclosed within the specification of the original application, as filed, in Figure 1, Summary of the Invention, Description of the Preferred Embodiment, Claims and Abstract of the Disclosure.

The Detailed Description of the Invention of the Substitute Specification begins at the bottom of page 3 and continues through page 18. Beginning at the bottom of page 3, and continuing on page 4 is a description of the first of the histamine H_2-receptor antagonists i.e., Nizatidine. Included in this description is a detailed description of the chemical composition of this drug and its recommended dosage for the maintenance of a healed duodenal ulcer. The use of Nizatidine as a histamine H_2-receptor antagonist was disclosed in the original application on Figure 1, paragraph 3 of the Summary of the Invention, the list of reference numbers utilized in the Drawing, paragraph 4 of page 1 of the Description of the Preferred Embodiment, paragraphs 3, 6, 9, and 12 of page 2 of the Description, original Claims 4, 13, 16, 19, 22, and 25 and the Abstract of Disclosure of the original application. The quantity of the Nizatidine which is disclosed in the Substitute Specification is also disclosed in the original application, as filed, on page 2 of the Description of the Preferred Embodiment,

paragraphs 3, 6, 9 and 12 (which disclose using 75 parts, 50 parts, and 150 parts of Nizatidine) and in Claims 13, 16, and 19 of the original application, as filed, which disclose use of the same quantities of this compound. The Substitute Specification further states that the recommended dosage should be around 300 mg. Basis for this quantity of this drug is contained in the original application, as filed, where it states that "...the histamine H_2-receptor antagonists are dosed as for use in maintenance treatment of duodenal ulcer." Summary of the Invention, paragraph 1. The dosage is also specifically disclosed in the PDR. Accordingly, there is basis in the original application, as filed, as well as the PDR to support the discussion of Nizatidine on pages 3 and 4 of the Substitute Specification. The applicant and his counsel specifically declare that no new subject matter has been added by this disclosure.

In a similar manner, the drug, Famotidine, is discussed on page 5 of the Substitute Specification. Support for the discussion of this drug is found in a similar manner throughout the original application, as filed, and the PDR.

In a similar manner the drug, Cimetidine, is discussed on page 6 of the Substitute Specification and is disclosed in the original application, as filed, as well as the PDR.

In a similar manner, the drug, Ranitidine is discussed on page 7 of the Substitute Specification. Support for this disclosure is

contained throughout the original application, as filed, as well as the PDR.

On page 8 begins the discussion of Psychotropic Active Drugs. Such drugs are discussed in the original application, as filed, in Figure 1, paragraph 1 of the Summary of the Invention, paragraphs 1 and 2 of the Description of the Preferred Embodiment, Claims 1, 2, 13, 14 and 15, and the Abstract of Disclosure. The detailed description of the chemical composition of the first psychoactive drug discussed, Olanzapine, as well as its mechanism of operation is contained in the original application, as filed and in the PDR. The amount of the Olanzapine that is to be used is also discussed in the original application, as filed, where it states that "The psychoactive drugs are dosed as recommended by the manufacturer. . ." (Paragraph 1 of the Summary of the Invention). See also the last paragraph of the first page of the Description of the Preferred Embodiments, paragraphs 1 and 2 of the second page of the Description of the Preferred Embodiment, and Claims 13, 14 and 15. Any of the detailed discussion of the chemical composition of Olanzapine, the specific content of the tablets, and the use of these drugs as antipsychotic drugs, is clearly disclosed either in the original application, as filed, or the PDR and would be well recognized by a person skilled in the art at the time of the filing of the original application.

In a similar manner, Clozapine, Risperidone and Quetiapine are

also discussed in the Substitute Specification on pages 9, 10 and 11. Similar discussions of each of these drugs are contained within the original application, as filed, and in the PDR. All of this subject matter was well known by persons skilled in the art at the time of the filing of the original application, as filed.

Beginning on the bottom of page 12 of the Substitute Specimen is a discussion of Mood-Altering Drugs, specifically Divalproex. The use of this drug is discussed on Figure 1, first paragraph of the second page of the Summary of the Invention, third paragraph of page 1, last paragraph of page 2, and the first two paragraphs of page 3 of the Description of the Preferred Embodiment, as well as Claims 3, 26, 27 and 28, and the Abstract of Disclosure. Once again, the quantity of this drug, which is recommended in the Substitute Specification, is disclosed in the first paragraph of the Summary of Invention of the original application, as filed, where it states that "the psychoactive drugs are dosed as recommended by the manufacturer. . ." (first paragraph), on the last paragraph of page 2 and the first two paragraphs of page 3 of the Description of the Preferred Embodiment, as well as Claims 25, 26 and 27 of the original application, as filed. With regard to any further description of this particular drug, its chemical nature or the dosage, these are disclosed in the PDR and would be well known by a person skilled in the art at the time of the filing of the original application.

In a similar manner the drug, Mirtazapine is discussed on pages 13 and 14 of the Substitute Specification and is well described in the original application, as filed, and in the PDR.

On page 15 of the Substitute Specification, the quantity of the antipsychotic drug or mood-stabilizing drug that is to be utilized is described in concentration of 10 to 90 percent, 30 to 60 percent and 50 percent of the combined drugs. These exact percentages are disclosed in the original application, as filed, in the second and third paragraphs of the Description of the Preferred Embodiment as well as in Claims 5 through 10, and the Abstract of the Disclosure.

The remaining description on pages 15 and 16 of the Substitute Specification describe well recognized methods of dosing the particular drugs and are disclosed both in the original application, as filed, and in the PDR.

Beginning at the last paragraph of page 16 and continuing on page 17 and 18 of the Substitute Specification are described the quantity of each of the drugs that should be utilized. In particular, at the bottom of page 17 and carrying over to page 18 are discussed the meaning of "safe and effective", which phrase is well recognized by persons skilled in the art. With regard to the specific quantities of the particular drug, these amounts were specifically disclosed in the original application, as filed, beginning on the last paragraph of page 1 of the Description of the

Preferred Embodiment and continuing until the second paragraph of page 3 and as claimed in Claims 13 through 27, and the Abstract.

The Abstract of Disclosure on page 21 of the Substitute Specification is merely a summary of the prior description contained in the original application, as filed, without adding new matter.

Each of the claims of the Substitute Specification are based on the disclosure in the Substitute Specification.

Accordingly, from a review of the Substitute Specification and a comparison with the original application, as filed, and the PDR, it is clear that no new subject matter has been added to the Substitute Specification.

Legal Analysis

The applicant respectfully requests that this objection to the Substitute Specification be withdrawn and that it be acknowledged that the disclosure in the Substitute Specification in no way changes the invention, as described from the original application. It is well recognized that "amendments to specification are not *ipso facto* new matter." (emphasis added.) *In Re: Wright*, (CCPA 1965) 145 USPQ 182. While it is true that matter not found in the application, as filed, may be new matter, it does not qualify as new matter unless it is a "departure from or an addition to the original disclosure."

The modifications to the original application, as filed, which are contained in the Substitute Specification are merely a restatement of the language from the original application, as filed, in a format which permits better review by the USPTO. The amendments to create the Substitute Specification do not depart from, nor add any feature to the invention, as described in the original disclosure. The Substitute Specification is merely a good-faith attempt to clarify the invention, as disclosed in the original application as filed. As stated in MPEP 608.04(a),

> . . . the addition of inherent characteristics such as chemical or physical properties, new structural formula, or new use may not be new matter. Only matter which is not contained in the original specification is new matter.

The applicant respectfully asserts that all of the disclosures contained in the Substitute Specification are supported by the original application, as filed, or the art which was incorporated by reference into the original application, namely the PDR. A person skilled in the art reviewing the original application, as filed, and the PDR, would well understand and be taught all that was contained in the Substitute Specification.

Accordingly, the applicant respectfully requests that the USPTO's refusal to enter the filed specification as a "Substitute Specification" under 1.125(b) be withdrawn and the Substitute Specification be accepted. As requested on p. 3 of the Office Action, the applicant and applicant's counsel specifically affirm

and declare that any information contained in the Substitute Specification which is considered to be additional matter is not new matter and consists of the same material incorporated by reference into the Substitute Specification as suggested by the Examiner in paragraph 4 of the Office Action. The applicant respectfully requests that the Substitute Specification filed November 28, 2001 be entered as it conforms with the requirements of 37 CFR 1.125(b). No essential subject matter which was not contained in the original application is disclosed in that Substitute Specification.